K120274

MAR - 2 2012

510(k) Summary

(As Required By 21 CFR 807.92(a))

A. Submitter Information

Submitter's name:	Codman & Shurtleff, Inc.
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Contact Person:	Kim Fonda
Date of Submission:	January 27, 2012

B. Trade/Device Name:	DELTAMAXX™ 18 Microcoil System
Common Name:	Artificial embolization device
Classification Name:	Neurovascular Embolization Device
Regulation Number:	Class II per 21 CFR 882.5950

C. Predicate Devices:

Device	Company	510(k) Number/ Concurrence Date	Product Code	Predicate For:
Primary: Micrus Microcoil System DELTAPAQ® 10 Stretch Resistant	Codman & Shurtleff, Inc (Previously Micrus Endovascular,Corp)	K080379 6/30/2008	HCG	Intended Use Design Materials Manufacturing Sterilization
Primary: Micrus Microcoil System, DELTAPAQ® 10 Cerecyte®	Codman & Shurtleff, Inc (Previously Micrus Endovascular,Corp)	K080437 5/8/2008	HCG	Intended Use Design Materials Manufacturing Sterilization
Micrus Microcoil System PRESIDIO® 18	Codman & Shurtleff, Inc (Previously Micrus Endovascular,Corp)	K062036 8/25/2006	HCG	Design

D. Device Description:

The intent of endovascular treatment using embolic microcoils is to pack the lumen of the aneurysm with the microcoil mass, thereby eliminating the influx of fresh blood into the aneurysm. The aneurysm neck will be covered with loops of coils to help eliminate the influx of fresh blood, a blood flow pathway is then re-established down the lumen of the parent artery, and the weakened wall of the aneurysm is isolated from arterial pressures. The existing blood and soft clot trapped within the lumen of the aneurysm begins to solidify, ultimately becoming hardened clot and scar tissue. The process will re-establish blood flow down the lumen of the parent artery and thromboses the aneurysm.

The DELTAMAXX ™ 18 Microcoil System consists of an embolic coil ("Microcoil") attached to a Device Positioning Unit (DPU), and is compatible with commercially available 2-tip marker microcatheters which have internal lumen diameters between 0.0165 inches and 0.019 inches. The DELTAMAXX ™ 18 Microcoils are provided in Stretch Resistant (SR) or Cerecyte® models and will be offered in lengths up to 60 cm and diameters ranging from 3 mm to 24 mm.

The DELTAMAXX™ 18 Microcoils are fabricated from the same platinum alloy wire used in the DELTAPAQ® Microcoils. The wire is wound into a primary coil (containing either a polypropylene (SR) or absorbable polymer suture (Cerecyte®) inside the wind and then formed into a secondary helical coil shape. The Microcoil is packaged in an introducer sheath designed to protect the coil in the packaging dispenser and to provide support for introducing the coil into the infusion catheter. The coil is the implantable segment of the device, and is detached from the device positioning unit by the Micrus Detachment Control System.

The DELTAMAXX™ 18 Microcoil System is a line extension to the currently marketed DELTAPAQ® 10 Microcoil System, as submitted in premarket notification numbers K080379 and K080437. The modifications include minor design changes required to expand the product line to include larger diameters and longer lengths as well as a minor manufacturing process change.

E. Intended Use:

The DELTAMAXX™ Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

F. Summary of technological characteristics of the proposed to the predicate device:

The DELTAMAXX™18 Microcoil System (including SR and Cerecyte® models) is substantially equivalent to the Micrus DELTAPAQ® 10 Microcoil System (including SR and Cerecyte® models). This modification expands the product line using existing technology and no new technological characteristics are being introduced with the proposed device.

The DELTAMAXX™18 Microcoil System has the same intended use as the DELTAPAQ® 10 Microcoil System and is similar with regard to design, manufacturing, sterilization process, and materials.

The DELTAMAXX™ 18 Microcoil System is also similar to the PRESIDIO® 18 Microcoil System with regard to the larger diameters and longer lengths.

A summary table including specifications of the proposed device compared with those of the predicate devices follows.

Comparative Information

Characteristic	DELTAMAXX™	DELTAPAQ® 10 (Primary Predicate)	PRESIDIO® 18 (Predicate)
Intended Use	The DELTAMAXX Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.	The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.	The Micrus Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and are also intended for arterial and venous embolizations in the peripheral vasculature.
Component and or material			
Implant material	Platinum Tungsten Alloy Wire	Platinum Tungsten Alloy Wire	Platinum Tungsten Alloy Wire
Internal suture material	SR – Polypropylene Cerecyte	SR – Polypropylene Cerecyte	Cerecyte
Primary wind OD	0.015"	0.0105"	0.015"
Profile of primary wind	Triangular	Triangular	Circular
Primary wind pattern (Deltawind Technology)	Rotated in a repeating pattern	Rotated in a repeating pattern	Cylindrical
Secondary Shape Coil OD	3mm – 24mm	1.5mm to 10mm	8mm – 20mm
Secondary shape	Helical	Helical	Spherical
Coil length	12 cm minimum 60cm maximum	2cm minimum 25cm maximum	30cm minimum 50cm maximum

Comparative Information (con't)

Characteristic	DELTAMAXX™	DELTAPAQ® 10 (Primary Predicate)	PRESIDIO® 18 (Predicate)
DPU Delivery System Length	150 cm	150 cm	150 cm
Microcatheter compatibility	Compatible with 2-tip marker micro catheters of ID from 0.0165" to 0.019"	Compatible with 2-tip marker micro catheters of ID from 0.014" to 0.017"	Compatible with 2-tip marker micro catheters of ID from 0.017" to 0.021"
Detachment System	Uses Micrus Connecting Cable	Uses Micrus Connecting Cable	Uses Micrus Connecting Cable
	Uses Micrus Detachment Control Box	Uses Micrus Detachment Control Box	Uses Micrus Detachment Control Box
Sterilization	E-Beam Radiation	E-Beam Radiation	E-Beam Radiation
Packaging	Packaged in a plastic hoop and enclosed in a pouch.	Packaged in a plastic hoop and enclosed in a pouch.	Packaged in a plastic hoop and enclosed in a pouch.

Note: The DELTAMAXX™ 18 Microcoil System is also similar to the MicroPlex Coil System- Cosmos™ (K093358) and the MicroPlex Coil System- Cosmos™ 18 (K102365) in regard to larger secondary coil diameter (24mm) and longer coil length (60cm).

G. Testing Summary:

Bench testing data demonstrates that the device performs according to its description and intended use, and establishes the performance characteristics of the modifications to this device. The DELTAMAXX™18 Microcoil System passed equivalent bench testing as compared to the DELTAPAQ 10 System and PRESIDIO 18 System predicate devices. Clinical testing was not required to establish substantial equivalence.

Results of verification and validation conducted on the DELTAMAXX™18 Microcoil System demonstrates that the system performs as designed, is suitable for the intended use, is substantially equivalent to the predicate device and therefore, does not raise any different questions of safety and effectiveness.

The following tests were conducted to verify the modified design for both Stretch Resistant and Cerecyte® models:

- Delivery Force Test
  - System Delivery Force
  - Microcatheter compatibility
- Secondary Shape Retention Test
  - Coil Secondary Shape OD
- Spring Constant Test
  - Primary Wind Coil Stiffness
- Detachment Zone Tensile Test
  - Coil Socket Ring Tensile Strength
  - Detachment Fiber Tensile Strength
  - Stretch resistance of suture/Tensile Strength
- Durability and Detachability Test
  - Durability-Cyclic advancement and retrieval of the microcoil system
  - Detachment of the microcoil from the delivery system
  - Coil damage after microcoil system delivery
  - Microcatheter compatibility

The proposed DELTAMAXX™18 Microcoil System is similar to the currently marketed DELTAPAQ ® 10 Microcoil System. The modifications include only minor design changes required to expand the product line to include larger diameters and longer lengths as well as a minor manufacturing process change.

The materials, suppliers, manufacturing process, packaging, and sterilization used in the DELTAMAXX™18 Microcoil System are identical to the material, suppliers, manufacturing process, packaging, and sterilization used in the current DELTAPAQ ® 10 Microcoil System with the exception of a minor manufacturing process change to the distal PET ring. The DELTAPAQ ® 10 Microcoil System was previously demonstrated to be biocompatible and the data to support the biocompatibility was provided to FDA in the predicate device premarket notifications K080379 (6/30/08) and K080437 (5/8/2008).

The DELTAMAXX™18 Microcoil System continues to meet all the same biocompatibility requirements as the predicate device and as specified by the ISO 10993 Part I, and the General Program Memorandum # G95-1 on Biological Evaluation of Medical Devices.

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Codman & Shurtleff, Inc., it is concluded that the DELTAMAXX™18 Microcoil System is substantially equivalent to the DELTAPAQ ® 10 Microcoil System, and therefore does not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Codman and Shurtleff, Inc.
c/o Ms. Kim Fonda
Manager Regulatory Affairs
325 Paramount Drive
Raynham, MA 02767-0350

MAR - 2 2012

Re: K120274
Trade/Device Name: DELTAMAXX™ 18 Microcoil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: January 27, 2012
Received: January 30, 2012

Dear Ms. Fonda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K120274

Device Name: DELTAMAXX™ 18 Microcoil System

The DELTAMAXX™ Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is also intended for arterial and venous embolizations in the peripheral vasculature.

Prescription Use __X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Jeffrey Toy

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120274